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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LE, EMILY M	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/601,719	FRIMANN, TINE HOLLAND	
	Examiner	Art Unit	
	Emily Le	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 November 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-13* is/are pending in the application.

4a) Of the above claim(s) *13* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 3-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Newly submitted claim 13 is directed to an invention that is distinct from the invention originally claimed. The newly submitted claim is directed a method of using a vaccine composition, whereas, the originally claimed invention is a vaccine formulation. Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 13 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Status of Claims

2. Claim 2 is cancelled. Claims 1 and 3-13 are pending. Claims 1 and 3-12 are under examination.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 3-5 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Ng et al., WO 98/34594, published 08/13/1998.

Applicant submits:

> Ng et al. patent does not anticipate the claimed invention because the teaching of Ng et al. relates to a combination of preservatives, which must use L-

histidine as a buffer to keep the vaccines at a pH of 7.0. Applicant's composition does not require L-histidine as a buffer to keep the pH at 7 and lacks the benzyl alcohol that is required by the reference. The terminology "consisting essentially of" has been used to exclude the presence of these two ingredients from Applicants' vaccine formulations. Applicant's compositions are not merely a combination of two compositions, each of which is taught by the prior art since the data in the application filed on pages 9-10 unequivocally shows the immunogenic effect of the vaccine when used to vaccinate guinea pigs and pigs and this combination could no way be ascertained form the Ng et al. reference. Applicant's submission has been considered, however, it is not found persuasive.

In the instant, Applicant's claimed invention remains to be anticipated by Ng et al. Ng et al. teaches the claimed vaccine formulation, which comprises an immunogen, pharmaceutically acceptable excipients, and the required combination of preservative that is instantly required of the claimed invention. The fact that the vaccine formulation of Ng et al. additionally comprises a buffer and an additional preservative does not render the teaching of Ng et al. as un-anticipatory to the claimed invention. Applicant's amendment to the claims to include "consisting essentially of" has been noted; however, the amended claims do not implicitly exclude the inclusion of the additional ingredients that Ng et al. teaches. Moreover, the ingredients, L-histidine as the buffer and benzyl alcohol as a preservative, are substances that would not materially affect the asserted novelty of the claimed invention.

Furthermore, Applicant's attention is directed to claim 4 of the instant application. Claim 4 defines the pharmaceutically acceptable excipients that can be included with the claimed invention as buffers and preservatives. Thus, in accordance with the language set forth in claim 4, the L-histidine and benzyl alcohol of Ng et al. can also be regarded as excipients of the claimed invention.

Lastly, regarding Applicant's assertion that the immunogenic effect of the vaccine could no way be ascertained from the teaching of Ng et al., Applicant's assertion have no merit. Applicant has not provided any evidence that the vaccine formulation of Ng et al. is not immunogenic. Furthermore, as noted the Ng et al. teaches the same formulation as that of the claimed invention. Any properties described by Applicant, such as immunogenicity, is an inherent property of the vaccine formulation itself. Thus, the vaccine formulation of Ng et al. would necessarily be immunogenic.

Ergo, Ng et al. continues to anticipate the claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 6 and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al. in view of Marciani, U.S. Patent No. 6080725, published 06/27/2000.

Applicant submits that the Ng et al. patent does not render obvious Applicant's invention. The Ng et al. reference relates to a combination of preservatives which must

use L-histidine as a buffer to keep the vaccines at a pH of 7.0. Applicant submits that Applicant's compositions do not require L-histidine as a buffer to keep the pH at 7 and lacks the benzyl alcohol which is required by the reference. The terminology "consisting essentially of" has been used to exclude the presence of these two ingredients from Applicants' vaccine formulations. Applicant additionally submit that Applicant's compositions are not merely a combination of two compositions, each of which is taught by the prior art since the data in the application filed on pages 9-10 unequivocally shows the immunogenic effect of the vaccine when used to vaccinate guinea pigs and pigs and this combination could no way be ascertained form the Ng et al. reference taken in further view of Marciani et al., which only teaches that saponin can have an antimicrobial activity and can be used in vaccine formulation. Marciani et al. in no way overcomes the deficiencies of Ng et al., as discussed above.

Applicant's submission has been considered, however, it is not found persuasive. In the instant, Applicant is arguing against only one of the references that are used in the above rejection. MPEP § 2145, item no. IV, states, "Applicant cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. In re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., Inc., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986)." In view of the guidance provided, Applicant's submission failed to provide why it is not obvious to use the teaching of both Ng et al. and Marciani et al.

Furthermore, contrary to Applicant's assertion, the teaching of Ng et al. is relevant. Ng et al. teaches a vaccine formulation, which comprises an immunogen,

pharmaceutically acceptable excipients, and the required combination of preservative that is instantly required of the claimed invention. The fact that the vaccine formulation of Ng et al. additionally comprises a buffer and an additional preservative does not render the teaching of Ng et al. as irrelevant to the claimed invention. Applicant's amendment to the claims to include "consisting essentially of" has been noted; however, the amended claims do not implicitly exclude the inclusion of the additional ingredients that Ng et al. teaches. Moreover, the ingredients, L-histidine as the buffer and benzyl alcohol as a preservative, are substances that would not materially affect the asserted novelty of the claimed invention.

Additionally, Applicant's attention is directed to claim 4 of the instant application. Claim 4 defines the pharmaceutically acceptable excipients that can be included with the claimed invention as buffers and preservatives. Thus, in accordance with the language set forth in claim 4, the L-histidine and benzyl alcohol of Ng et al. can also be regarded as excipients of the claimed invention.

Lastly, regarding Applicant's assertion that the immunogenic effect of the vaccine could no way be ascertained from the teaching of Ng et al., Applicant's assertion have no merit. Applicant has not provided any evidence that the vaccine formulation of Ng et al. is not immunogenic. Furthermore, as noted the Ng et al. teaches the same formulation as that of the claimed invention, with the exception of limitations recited in claims 6 and 10-11. Any properties described by Applicant, such as immunogenicity, is an inherent property of the vaccine formulation itself. Thus, the vaccine formulation of

Ng et al. would necessarily be immunogenic. Ergo, Ng et al. is relevant to the claimed invention.

7. Claims 7-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al.

Applicant submits that the Ng et al. patent does not render obvious Applicant's invention. The Ng et al. reference relates to a combination of preservatives comprising methyl and propyl parabens, benzyl alcohol and 2-phenoxyethanol which must use L-histidine as a buffer to keep the vaccines at a pH of 7.0. Applicant submits that Applicant's compositions do not require L-histidine as a buffer to keep the pH at 7 and lacks the benzyl alcohol which is required by the reference. The terminology "consisting essentially of" has been used to exclude the presence of these two ingredients form Applicants' vaccine formulations. Applicant's compositions are not merely a combination of two compositions, each of which is taught by the prior art since the data in the application filed on pages 9-10 unequivocally shows the immunogenic effect of the vaccine when used to vaccinate guinea pigs and pigs and this combination could no way be ascertained form the Ng et al.

Applicant's submission has been considered, however, it is not found persuasive. Contrary to Applicant's assertion, the teaching of Ng et al. is relevant. Ng et al. teaches a vaccine formulation, which comprises an immunogen, pharmaceutically acceptable excipients, and the required combination of preservative that is instantly required of the claimed invention. The fact that the vaccine formulation of Ng et al. additionally comprises a buffer and an additional preservative does not render the teaching of Ng et

al. as irrelevant to the claimed invention. Applicant's amendment to the claims to include "consisting essentially of" has been noted; however, the amended claims do not implicitly exclude the inclusion of the additional ingredients that Ng et al. teaches. Moreover, the ingredients, L-histidine as the buffer and benzyl alcohol as a preservative, are substances that would not materially affect the asserted novelty of the claimed invention.

Additionally, Applicant's attention is directed to claim 4 of the instant application. Claim 4 defines the pharmaceutically acceptable excipients that can be included with the claimed invention as buffers and preservatives. Thus, in accordance with the language set forth in claim 4, the L-histidine and benzyl alcohol of Ng et al. can also be regarded as excipients of the claimed invention.

Lastly, regarding Applicant's assertion that the immunogenic effect of the vaccine could no way be ascertained from the teaching of Ng et al., Applicant's assertion have no merit. Applicant has not provided any evidence that the vaccine formulation of Ng et al. is not immunogenic. Furthermore, as noted the Ng et al. teaches the same formulation as that of the claimed invention, with the exception of limitations recited in claims 7-8. Any properties described by Applicant, such as immunogenicity, is an inherent property of the vaccine formulation itself. Thus, the vaccine formulation of Ng et al. would necessarily be immunogenic. Ergo, Ng et al. is relevant to the claimed invention.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ng et al. in view of Allan et al. (U.S. Patent No. 6217883).

The claim limits the immunogen to an inactivated porcine parvovirus.

The significance of Ng et al. is discussed above. To summarize, Ng et al. teaches a vaccine formulation.

Ng et al. does not teach an inactivated porcine parvovirus.

However, Allan et al. teaches inactivated porcine parvovirus and its use in a vaccine formulation for use against the porcine multisystemic wasting syndrome (PMWS).

One of ordinary skill in the art at the time the invention was made would have been motivated combine the teaching of Ng et al. and Allan et al. to produce a vaccine that comprises an inactivated porcine parvovirus to provide treatment against the porcine multisystemic wasting syndrome (PMWS).

One of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of success for combining Ng et al. and Allan et al. because Ng et al. teaches the vaccine formulation and Allan et al. teaches the use of inactivated porcine parvovirus in a vaccine formulation for use against the porcine multisystemic wasting syndrome (PMWS).

Therefore, one of ordinary of ordinary skill in the art at the time the invention was made would have had a reasonable expectation of producing the claimed invention, absent unexpected results to the contrary.

Conclusion

9. No claim is allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily Le whose telephone number is (571) 272 0903. The examiner can normally be reached on Monday - Friday, 8 am - 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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